IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC. and EMORY UNIVERSITY, Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, Defendant.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs"), for their complaint against Amneal Pharmaceuticals LLC ("Amneal"), hereby allege as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code.

The Parties

2. Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. Emory is a non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

4. On information and belief, defendant Amneal is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807-2863.

Jurisdiction and Venue

5. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21 of the United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

6. On information and belief, this Court has personal jurisdiction over Amneal.

7. On information and belief, Amneal is a limited liability company registered with the Delaware Department of State, Division of Corporations, under file number 3809030.

8. On information and belief, Amneal maintains a registered agent for service of process in Delaware, the Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

9. On information and belief, Amneal is a generic pharmaceutical company in the business of marketing and distributing generic drug products, and derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in Delaware.

10. On information and belief, Amneal, itself or through one of its wholly-owned subsidiaries, manufactures pharmaceutical drug products that are sold and used throughout the United States, including in Delaware.

11. On information and belief, residents of Delaware purchase pharmaceutical drug products from Amneal in Delaware.

12. On information and belief, Amneal holds a Delaware pharmacy wholesale license (Nos. A4-0001536 and A4-0002253) and a Delaware controlled substances distributor/manufacturer license (No. DM 0006588).

13. On information and belief, Amneal's submission of Abbreviated New Drug Application ("ANDA") No. 209721, discussed below, indicates Amneal's intention to engage in

the commercial manufacture, use, sale and/or importation of products that will compete directly with Gilead's Truvada® product, which is currently being sold throughout the United States, including in Delaware. On information and belief, Amneal will sell tablets containing 100 mg/150 mg, 133 mg/200 mg, and 167 mg/250 mg of emtricitabine/ tenofovir disoproxil fumarate, respectively, for the use for which Amneal seeks approval in ANDA No. 209721, if approved, throughout the United States, including in Delaware.

14. On information and belief, Amneal has availed itself of this Court's jurisdiction by filing counterclaims in this District, and has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g.*, *Endo Pharms. Inc. v. Amneal Pharms. LLC*, 1:14-cv-1382-RGA (D. Del.); *Forest Labs., Inc. v. Amneal Pharms. LLC*, 1:14-cv-508-LPS (D. Del.).

15. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b). Specifically, venue is proper in Delaware because Amneal is incorporated in Delaware.

Background

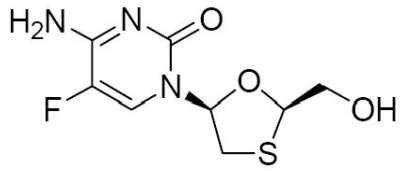
16. Gilead is the holder of New Drug Application ("NDA") No. 21-752 which relates to tablets containing emtricitabine and tenofovir disoproxil fumarate. On August 2, 2004, the United States Food and Drug Administration ("FDA") approved the use of the tablets containing 200mg of emtricitabine and 300mg of tenofovir disoproxil fumarate for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Truvada®. On March 10, 2016, the FDA approved Truvada® in the following emtricitabine/tenofovir disoproxil fumarate dosage strengths for the treatment of HIV-1 infection in pediatric patients: 167mg/250mg, 133mg/200mg, and 100mg/150mg ("low dosage strengths").

17. United States Patent No. 6,642,245 ("the '245 Patent," copy attached as Exhibit A), entitled "Antiviral Activity and Resolution of 2-Hydroxymethyl-5-(5-fluorocytosin-1-yl)

-1,3-oxathiolane," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2003. The '245 Patent claims, *inter alia*, methods for treating HIV infection in humans with emtricitabine (one of the active ingredients in Truvada®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Truvada®.

18. United States Patent No. 6,703,396 ("the '396 Patent," copy attached as Exhibit B), entitled "Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers," was duly and legally issued by the United States Patent and Trademark Office on March 9, 2004. The '396 Patent claims, *inter alia*, emtricitabine (one of the active ingredients in Truvada®), and is listed in the FDA Orange Book for Truvada®.

19. Emtricitabine is a compound that has a molecular formula of $C_8H_{10}FN_3O_3S$, and which has the following chemical structure:



20. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Emtriva® label is "5-fluoro-1-[(2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine." Two chemical names recited for emtricitabine in the '245 Patent are "(–)-β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane" and "β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane." Two chemical names recited for emtricitabine in the '396 Patent are "(–)-cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one" and "(–)-enantiomer of cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one."

21. The named inventors on the ’245 and ’396 Patents are Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi.

22. Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi assigned the ’245 and ’396 Patents to Emory.

23. Pursuant to an agreement entered into between Gilead and Emory, Gilead has substantial rights in the ’245 and ’396 Patents, including, but not limited to, rights associated with being a licensee of the ’245 and ’396 Patents, and the right to sue for infringement of the ’245 and ’396 Patents.

COUNT 1
Infringement of U.S. Patent No. 6,642,245

24. Plaintiffs repeat and reallege paragraphs 1-23 above as if set forth herein.

25. On information and belief, Amneal submitted or caused to be submitted ANDA No. 209721 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate (i.e., 100mg/150mg, 133mg/200mg, and 167mg/250mg) for the purpose of treating HIV infection.

26. By letter dated May 31, 2017 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the “May 31, 2017 Notice Letter”), Amneal notified Plaintiffs that it had submitted ANDA No. 209721 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate prior to the expiration of the ’245 Patent. This complaint has been filed within 45 days of Plaintiffs’ receipt of the May 31, 2017 Notice Letter.

27. In its May 31, 2017 Notice Letter, Amneal notified Plaintiffs that, as a part of ANDA No. 209721, it had filed a certification of the type described in 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '245 Patent. Paragraph IV requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '245 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

28. Amneal alleged in its May 31, 2017 Notice Letter that Claims 1, 2, 4, 6, 7 and 8 of the '245 Patent are invalid and that Claims 3, 5, and 9-22 of the '245 Patent would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 209721.

29. The May 31, 2017 Notice Letter does not allege non-infringement of Claims 1, 2, 4, 6, 7 and 8 of the '245 Patent.

30. The May 31, 2017 Notice Letter does not provide the full and detailed statement of Amneal's factual and legal basis to support its non-infringement and invalidity allegations as to the '245 Patent.

31. Accordingly, the May 31, 2017 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

32. By filing ANDA 209721 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate before the '245 Patent's expiration, Amneal has committed an act of infringement of the '245 Patent under 35 U.S.C. § 271(e)(2).

33. On information and belief, Amneal lacked a good faith basis for alleging invalidity when ANDA No. 209721 was filed and when the Paragraph IV certification was made. Amneal's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '245 Patent.

34. Amneal's submission of ANDA No. 209721 and service of the May 31, 2017 Notice Letter indicates a refusal to change its current course of action.

35. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for which Amneal seeks approval in ANDA No. 209721, if approved, will infringe one or more claims of the '245 Patent.

36. On information and belief, Amneal will directly or indirectly infringe at least Claim 1 of the '245 Patent. Claim 1 recites a "method for treating HIV infection in humans comprising administering an effective amount of [emtricitabine], or its physiologically acceptable salt, optionally in a pharmaceutically acceptable carrier." On information and belief, Amneal will infringe Claim 1 of the '245 Patent because the product for which it seeks approval in ANDA No. 209721 will be labeled for and used to treat HIV infection in humans with an effective amount of emtricitabine. In its May 31, 2017 Notice Letter, Amneal does not allege that Claim 1 would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of its

proposed product that is the subject of ANDA No. 209721. For the same reasons, on information and belief, Amneal will likewise infringe Claims 2, 4, 6, 7 and 8 of the '245 Patent.

37. On information and belief, the tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for the use for which Amneal seeks approval in ANDA No. 209721, if approved, will be administered to human patients in an effective amount for treating HIV infection. Such administration will infringe at least one claim of the '245 Patent, as described in the preceding paragraph. On information and belief, this administration will occur at Amneal's active behest and with its intent, knowledge and encouragement. On information and belief, Amneal will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '245 Patent. Further, by filing ANDA No. 209721 with a Paragraph IV certification, Amneal admits that it has knowledge of the '245 Patent.

38. The May 31, 2017 Notice Letter does not allege and does not address unenforceability of any claims of the '245 Patent. By not addressing unenforceability of any claims of the '245 Patent in its May 31, 2017 Notice Letter, Amneal admits that all of the claims of the '245 Patent are enforceable.

COUNT 2
Infringement of U.S. Patent No. 6,703,396

39. Plaintiffs repeat and reallege paragraphs 1-23 above as if set forth herein.

40. On information and belief, Amneal submitted or caused to be submitted ANDA No. 209721 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate (i.e., 100mg/150mg, 133mg/200mg, and 167mg/250mg) for the purpose of treating HIV infection.

41. In its May 31, 2017 Notice Letter, Amneal notified Plaintiffs that it had submitted ANDA No. 209721 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate prior to the expiration of the '396 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the May 31, 2017 Notice Letter.

42. In its May 31, 2017 Notice Letter, Amneal notified Plaintiffs that, as a part of its ANDA No. 209721, it had filed a Paragraph IV certification with respect to the '396 Patent. Paragraph IV requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '396 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

43. Amneal alleged in its May 31, 2017 Notice Letter that Claims 1-7, 13, 15 and 16 of the '396 Patent are invalid and that Claims 8-12, 14 and 17-28 would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 209721.

44. The May 31, 2017 Notice Letter does not allege non-infringement of Claims 1-7, 13, 15 and 16 of the '396 Patent.

45. The May 31, 2017 Notice Letter does not provide the full and detailed statement of Amneal's factual and legal basis to support its non-infringement and invalidity allegations as to the '396 Patent.

46. Accordingly, the May 31, 2017 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

47. By filing ANDA No. 209721 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate before the '396 Patent's expiration, Amneal has committed an act of infringement of the '396 Patent under 35 U.S.C. § 271(e)(2).

48. On information and belief, Amneal lacked a good faith basis for alleging invalidity when ANDA No. 209721 was filed and when the Paragraph IV certification was made. Amneal's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '396 Patent.

49. Amneal's submission of ANDA No. 209721 and service of the May 31, 2017 Notice Letter indicates a refusal to change its current course of action.

50. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for which Amneal seeks approval in ANDA No. 209721, if approved, will infringe one or more claims of the '396 Patent.

51. On information and belief, Amneal will directly or indirectly infringe at least Claim 2 of the '396 Patent. Claim 2 recites "[emtricitabine] or a pharmaceutically acceptable salt, ester or salt of an ester thereof." On information and belief, Amneal will infringe Claim 2 of the '396 Patent because the product for which it seeks approval in ANDA No. 209721 will contain

emtricitabine as the active ingredient. In its May 31, 2017 Notice Letter, Amneal does not allege that Claim 2 would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of its proposed product that is the subject of ANDA No. 209721. For the same reasons, on information and belief, Amneal will also infringe Claims 1, 3-7, 13, 15 and 16 of the '396 Patent.

52. On information and belief, the tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for the use for which Amneal seeks approval in ANDA No. 209721, if approved, will infringe at least one claim of the '396 Patent, as described in the preceding paragraph. On information and belief, the manufacture of these tablets will occur at Amneal's active behest and with its intent, knowledge and encouragement. On information and belief, Amneal will actively encourage, aid and abet the manufacture of these tablets with knowledge that it is in contravention of Plaintiffs' rights under the '396 Patent. Further, by filing ANDA No. 209721 with a Paragraph IV certification, Amneal admits that it has knowledge of the '396 Patent.

53. The May 31, 2017 Notice Letter does not allege and does not address unenforceability of any claims of the '396 Patent. By not addressing unenforceability of any claims of the '396 Patent in its May 31, 2017 Notice Letter, Amneal admits that all of the claims of the '396 Patent are enforceable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Amneal's ANDA No. 209721 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '245 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(b) A judgment declaring that the effective date of any approval of Amneal's ANDA No. 209721 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '396 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(c) A judgment declaring that the '245 Patent remains valid and enforceable, and that one or more claims have been infringed by Amneal;

(d) A judgment declaring that the '396 Patent remains valid and enforceable, and that one or more claims have been infringed by Amneal;

(e) A permanent injunction against any infringement of the '245 Patent by Amneal, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(f) A permanent injunction against any infringement of the '396 Patent by Amneal, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(g) A judgment that Amneal's conduct is exceptional in this case;

(h) An award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(i) To the extent that Amneal has committed any acts with respect to the subject matter claimed in the '245 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(j) To the extent that Amneal has committed any acts with respect to the subject matter claimed in the '396 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(k) Costs and expenses in this action; and

(l) Such other relief as this Court may deem proper.

Dated: July 13, 2017

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market St., 12th Floor
Wilmington, DE 19801
Tel: 302-777-0300
Fax: 302-777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiffs Gilead Sciences, Inc. and Emory University

OF COUNSEL:

Christopher Borello
Frederick Millett
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104